

FILED

NOV 14 2017

THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
Eastern Division

KATE MCKINLEY,
1255 Town Center Road Unit 4D
Vernon Hills, IL 60061

Plaintiff,

v.

ABBVIE, INC.
1 North Waukegan Road
North Chicago, IL 60064

Defendant.

17 CV 8255
JUDGE CASTILLO
MAGISTRATE JUDGE GILBERT

**CIVIL COMPLAINT FOR EQUITABLE AND
MONETARY RELIEF AND DEMAND FOR JURY TRIAL**

Plaintiff Kate McKinley sues Defendant AbbVie, Inc. (AbbVie) for violation of the anti-retaliation provision of the False Claims Act, 31 U.S.C. § 3730(h) (FCA).

INTRODUCTION

1. McKinley worked in the pharmaceutical sales industry for almost twenty years and was a longtime, top-performing employee.
2. McKinley joined Abbott Laboratories in 2000, which spun off as AbbVie, Inc., where she was the Sales Director for the Endocrinology Franchise and received top-tier individual performance ratings throughout her tenure.
3. Throughout her career at AbbVie, McKinley strictly held to company messaging rules, and ensured compliance with the company's messaging rules by her reports, despite the limited

training and lack of guidance from AbbVie.

4. In 2012, Abbott, and ultimately AbbVie, entered into a Corporate Integrity Agreement with the Department of Health and Human Services Office of the Inspector General after another pharmaceutical sales group violated messaging requirements.

5. During the latter part of 2016, a competitor wrote a letter to AbbVie alleging the Endo Franchise at AbbVie engaged in illegal sales tactics, and AbbVie launched an investigation into the sales practices of its Endo pharmaceutical sales representatives by searching e-mails for key words and phrases such as “average selling price,” “ASP erosion,” and “market dynamics.”

6. In December 2016 AbbVie interviewed McKinley as part of the investigation, and before the investigation began, the company informed McKinley the interview was not about her, she was not the target of the investigation, and she could not take notes during the interview. The interviewer told McKinley that the interview was about better understanding communication around ASPs for the Endo franchise.

7. McKinley participated in the compliance interview where she exposed large-scale, company-wide FCA compliance and training failures, recommended increased training to avoid company violations of the FCA, and was thereafter terminated.

8. Following her termination, the company implemented new training and completely changed its messaging rules, demonstrating clear understanding that McKinley had identified potentially major violations of the FCA.

JURISDICTION AND VENUE

9. This Court has personal jurisdiction over AbbVie because it maintains its principal place of business in this district.

10. This Court has jurisdiction over the subject matter of this complaint pursuant to 28

U.S.C. § 1331, because this is an action arising under the laws of the United States, specifically the FCA, 31 U.S.C. § 3730(h).

11. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b) because it is the judicial district where many of the unlawful employment practices are alleged to have been committed, and because AbbVie maintains its principle place of business in this venue.

PARTIES

12. Plaintiff McKinley is a resident of Illinois and a citizen of the United States. McKinley was an employee of Defendant AbbVie.

13. Defendant AbbVie is a Delaware corporation with its principal place of business in North Chicago, Illinois. AbbVie is a biopharmaceutical company that develops and manufactures medicines and therapies.

FACTUAL ALLEGATIONS

McKinley built a successful career in pharmaceutical sales management during a career spanning seventeen years at Abbott and AbbVie.

14. McKinley obtained her Bachelor of Science in Business Administration degree in marketing, management, and psychology as well as her Masters of Business Administration degree, *summa cum laude*, from the Collins College of Business at the University of Tulsa.

15. McKinley began her pharmaceutical sales career in September 2000 as a Sales Representative at Knoll Pharmaceuticals, which Abbott Laboratories purchased in November 2000. McKinley continued as a Sales Representative for Abbott's Endocrine Franchise.

16. In November 2001, after her first year, Abbott promoted McKinley to Regional Sales Trainer.

17. Abbott again promoted McKinley in March 2002 to District Manager where McKinley

led a sales team that promoted Abbott products Meridia, Synthroid, and TriCor.

18. In or about May 2004 Abbott promoted McKinley to Senior District Manager and again in January 2007 to Area Training Manager responsible for the West and South areas.

19. Abbott promoted McKinley to Regional Sales Manager for Primary Care in January 2008 where she delivered approximately \$75 million in top-line sales in the country's largest primary care geographic region.

20. In May 2012, Abbott promoted McKinley to Regional Manager for the Endocrinology Franchise.

21. Effective January 1, 2013 AbbVie spun-off from Abbott Laboratories, and McKinley became an employee of AbbVie.

22. McKinley continued as a Regional Manager for AbbVie until December 2014 when AbbVie promoted her to Sales Director for the Endocrinology Franchise.

23. As Sales Director, McKinley managed more than 240 regional managers, sales leaders, and sales representatives directly or indirectly while delivering the Endocrinology Franchise's highest volume growth in more than nine years.

24. Throughout her tenure with AbbVie and its predecessors, McKinley had a record of excellent performance.

25. McKinley received "meets" or "exceeds" expectations for all annual performance reviews over her career.

26. During her first year, McKinley received the Rookie of the Year Award as well as the Sales Representative Summit Award.

27. In 2005 McKinley received the District Manager Summit Award.

28. In 2006 McKinley won the Innovation Award.

29. Abbott appointed McKinley to the Regional Manager Development Task Force in 2007.

30. McKinley was the Most Valuable Account Executive, the Number One Pinnacle Performer, and recipient of the President's Award for 2011.

31. From 2011 until 2014 McKinley won four consecutive Summit Awards. The company awarded her a Rolex watch and a luxury company vehicle for her achievement.

32. McKinley won Regional Manager of the Year in 2013.

33. In 2016 McKinley again received the President's Award.

McKinley suffers discriminatory comments from her superiors for being female.

34. During her tenure as a Sales Director, Jim Hynd, Vice President, through Marianne Sutcliffe, Vice President of Sales and Marketing for Endocrinology, repeatedly made discriminatory comments to McKinley based on her sex.

35. Hynd told Sutcliffe he wanted McKinley disciplined for bringing her four-month old child on a trip to Hawaii and breastfeeding the child during the trip. McKinley had won the trip as a reward for her performance, she excused herself for short breaks during the trip to breastfeed, and she did not miss any work responsibilities or bring the child to any work events.

36. McKinley spent thousands of dollars of her own money to bring her in-laws to Hawaii to care for her four-month-old child. The child was not visible to any AbbVie employees on the week-long trip. Hynd only became aware of McKinley's child's presence in Hawaii when meeting planners went into McKinley's room without warning and saw a crib and diapers in the hotel room.

37. On another occasion Hynd told Sutcliffe to discipline McKinley for wearing a dress he claimed caused "chatter." McKinley previously wore the dress on several business occasions without issue.

38. Upon return from Maternity Leave, McKinley asked Doreen Gascoigne, Human Resources Senior Manager, about AbbVie's policy on shipping breast milk home while on business trips. McKinley understood it was a standard practice in the pharmaceutical industry as several benchmark companies had policies in place to ship milk home for working mothers.

39. Gascoigne informed McKinley that AbbVie would not cover the cost of shipping breast milk and McKinley would have to pay for it out of her own pocket.

40. Several weeks later, Sutcliffe informed McKinley that Hynd asked Sutcliffe why McKinley was asking AbbVie to pay for shipping breast milk. Hynd informed McKinley that Gascoigne told him McKinley had asked.

41. Sutcliffe informed McKinley on one occasion that if she wanted to have a second baby, McKinley had better "hurry up" and have the baby before the launch of a new drug.

42. McKinley brought her concerns to Sutcliffe that Hynd was treating McKinley differently due to her gender.

43. Sutcliffe responded by telling McKinley that women in the pharmaceutical sales industry were held to a higher standard and that McKinley should get used to it if she wanted to work in the Home Office.

44. McKinley mentioned that she may raise these concerns to human resources and Sutcliffe discouraged McKinley from reporting her concerns.

45. Sutcliffe repeatedly stated she did not trust HR, and on at least one occasion Sutcliffe told McKinley not to go to Human Resources any longer, stating, "HR is not your friend."

Abbott Enters into a Corporate Integrity Agreement and initiates its Challenger Sales Method.

46. In 2012 Abbott entered into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of the Inspector General.

47. This CIA required Abbott to self-report any manipulation on the part of its salesforce of the cost and price information related to drugs covered under Medicare, and was to be effective for five years.

48. The CIA was designed to promote compliance with statutes, regulations, and written directives of Medicare, Medicaid, and other federal healthcare programs.

49. The CIA arose from Abbott's Depakote group that violated messaging rules pertaining to the drug.

50. After AbbVie's spin-off from Abbott, the CIA also applied to AbbVie.

51. Under the conditions required by the CIA, Abbott and AbbVie were required to have a certifying employee from each business unit to sign a certification stating:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or function area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the ____ [insert name of the department or functional area] with all applicable Federal healthcare program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Abbott policies, and I have taken steps to promote such compliance...”

52. Abbott and AbbVie were also required to provide general and specific training to every covered person, and covered persons engaged in promotional functions or product related functions were required to receive additional hours of training.

53. Abbott and AbbVie were required to annually review and revise the company's training.

54. AbbVie did not implement any specific ASP or pricing training to the entire sales force other than quarterly general compliance training.

55. These compliance trainings did not include how to handle internal or external discussions of price and average sale price (“ASP”).

56. Training administered to the pharmaceutical sales representatives covered business that was not directly relevant to the representatives’ jobs such as working with officials outside of the United States. Sales representatives did not receive training on important topics directly relevant to the job, such as communications to physicians about pricing and competitors.

57. Marianne Sutcliffe challenged the sales force not to “walk around with your tails between your legs, because Lupron and AbbVie are the market leaders, and you need to act like it.”

58. In or about 2012, AbbVie introduced the “Challenger” sales method to its pharmaceutical sales representatives. The Endo franchise received this training in 2013.

59. Prior to implementation of the Challenger sales method, AbbVie representatives had a linear selling model: sales representatives opened by discussing the features and benefits of the product, and followed with probing questions to the physician to get clarity.

60. The Challenger sales method is based on a book called “The Challenger Sale: Taking Control of the Customer Conversation,” authored by Matthew Dixon and Brent Adamson.

61. The book jacket states that “Challengers provide customers with surprising insight about how they make or save money. Rather than acquiescing to the customer’s every demand or objection, they are assertive, pushing back when necessary and taking control of the sale.”

62. When using Challenger sales, rather than starting with discussing the product, a sales representative would finish by discussing the product with a physician.

63. This Challenger sales model had three steps: 1) deliver insight, 2) discuss the impact to the physician, and 3) discuss the features and benefits of the product.

64. The Challenger sales method differed from prior tactics because it was more consultative

and aggressive, which was designed to get the physician's attention.

65. This new method heavily emphasized the importance of sales representatives knowing the customer's economics and forced pharmaceutical sales representatives to be bold in discussing price and financials of the physician.

66. For example, Page 21 of the book features a passage that reads, "Challengers are assertive—they tend to "press" customers a little—both on their thinking and around things like pricing."

67. Page 11 of the book features a passage comparing challenger sales to other salespersons arguing that challengers, "outperform by nearly 200%. As sales become more complex, the gap between core and star performers widens dramatically."

68. Page 23 of the book outlines the relevant characteristics that lead to challenger representatives outperforming other sales representatives, stating, "In our analysis, of the 44 or so attributes we tested, 6 of them showed up as statistically significant in defining someone as a Challenger rep:

- Offers the customer unique perspectives
- Has strong 2 way communication skills
- Knows the individual customer's value drivers
- Can identify economic drivers of the customer's business
- Is comfortable discussing money
- Can pressure the customer."

69. When rolling out the Challenger sales method, AbbVie did not provide any clear training or guidance on what pharmaceutical sales representatives were or were not allowed to say about price and economics.

70. In materials provided to staff on how to implement Challenger selling, AbbVie suggested that all training materials be consistent with “approved messaging,” but no such approved messaging existed regarding price and ASP.

71. What training on messaging that did exist clearly allowed representatives to discuss pricing and ASP in certain contexts, both internally and externally.

72. As part of its training on Challenger selling, the Company offered up a brief disclaimer that certain aspects of Challenger are not appropriate in the Pharma setting. This disclaimer was known as “Challenger Demystified.”

73. In the same training, the sales force was encouraged to come up with their own insights from information in the public domain relating to general healthcare and the “business landscape,” which necessarily entails use of un-reviewed and unapproved messaging.

74. For example, AbbVie’s limited guidelines stated promotional and non-promotional material must:

- a. “Not be false, deceptive or misleading in any manner;”
- b. “Be medically accurate, and when required, contain substantiation of claims;”
- c. “Be consistent with the current approved Label or Labeling;”
- d. “Present balanced information about the benefits and risks of a product, where required;”
- e. “Include proper usage or prescribing information, where required.”

75. Sales representatives were not given “insights,” the first step in the Challenger sales method, but were rather encouraged to create their own in line with these Challenger sales principles.

76. AbbVie encouraged sales representatives to search for insights in the public domain, in-

cluding the Internet, publications, and gathering information from customers.

77. McKinley's supervisor, Marianne Sutcliffe, Vice President of Sales and Marketing for Endocrinology, never questioned her ethics or compliance.

78. Sutcliffe, along with other senior executives, actively participated in communications McKinley distributed to her team and never raised a concern over inappropriate messaging, communication, or direction given.

An AbbVie competitor alleges violations of the Anti-Kickback statute, and AbbVie launches an investigation.

79. AbbVie's flagship product is the drug Humira, an injectable \$16 billion drug, representing roughly 60% of total AbbVie sales.

80. Humira is a Medicare Part D drug, which requires the Company to be well-versed in all aspects of part D reimbursement; Lupron is a Medicare Part B drug.

81. During the second half of 2016, Tolmar, AbbVie's competitor, sent a letter to AbbVie alleging that AbbVie was engaged in illegal sales tactics.

82. Tolmar manufactures the drug Eligard, the primary competing drug to Lupron, which is the AbbVie drug McKinley's franchise sold. Lupron maintains approximately 70% market share, and Eligard 20%.

83. AbbVie is developing a new billion-dollar drug, Elagolix, that requires government approval, which is projected to launch in 2018 and reach \$2 billion in peak sales.

84. Elagolix will be AbbVie's fifth launch. The previous 4 failed, putting even more pressure on the upcoming launch.

85. Sutcliffe and Hynd repeatedly stated to McKinley that there have been four failed launches and AbbVie cannot afford a fifth failed launch.

86. Due to the pressure surrounding the launch of Elagolix, AbbVie sought to cover up any

actual or perceived problems that could jeopardize this roll-out.

87. Any issues with improper messaging that violated the CIA could also be detrimental to AbbVie if sales of Humira were suspended or affected.

88. In response to Tolmar's allegations, AbbVie engaged its Office of Ethics and Compliance (OEC) to investigate sales practices.

89. Beginning in or about September 2016, the OEC reviewed all internal and external email communications based on key phrases that could indicate AbbVie marketers engaged in problematic communications.

90. Such key phrases included "market dynamics," "ASP [Average Sale Price] erosion," and "return to practice (RTP)."

91. The Sales Representatives, District Managers, and Regional Managers reporting to McKinley understood that they were not to discuss physician profit margins with customers.

92. However, information about reimbursement is publicly available for a physician to determine on his or her own what would be most profitable.

93. Until the last quarter of 2016, AbbVie communicated and tracked reimbursement information franchise-wide. Since the start of her employment, McKinley and many others received regular, company-sanctioned copies of quarterly ASP information.

94. Medicare publishes the average sales price for all covered drugs.

95. Lupron and Eligard have the same basic chemical properties, expressed by the Food and Drug Administration (FDA) J-Code, but the drugs differ in how they are delivered.

96. A physician who researches the average sale price of these two products and determines that Eligard would make more money per dose can calculate the profit margin. The difference in the acquisition price, when factored together with the Medicare reimbursement rates, allows the

physician to calculate the “return to practice.”

97. While physicians are allowed to do this calculation on their own, drug sales representatives are prohibited from communicating directly about these issues, a practice commonly referred to as “marketing to the spread” or “selling to the spread.”

AbbVie interviews McKinley during its investigation.

98. The next phase of the investigation began in December 2016 when AbbVie OEC investigators conducted live interviews of fifteen (15) employees.

99. The focus of these interviews was language used in discussions of Lupron with physicians.

100. On or about December 5, 2016, McKinley received an e-mail from Will Lee from the Office of Ethics and Compliance asking McKinley to meet in person on December 8, 2016.

101. McKinley spoke with Sutcliffe asking what the interview was about.

102. Sutcliffe informed McKinley that it was an investigation sparked by the Tolmar letter and that, “As long as no one says anything stupid, we should be fine.”

103. McKinley asked Sutcliffe what this meant, and Sutcliffe responded, “Everyone knows what they can and cannot say. It’s all laid out in Mick’s e-mail.”

104. Sutcliffe informed McKinley that she did not read e-mails about the team’s success stories anymore. McKinley responded by voicing her concerns.

105. On or about December 8, 2016 Lee interviewed McKinley. Lee told McKinley that the purpose of the interview was to obtain information and said that she should not worry about termination.

106. Lee further stated he was interviewing others and he would notify McKinley when the investigation closed and if it would impact anyone on her team.

107. Lee conducted a majority of the live interviews.
108. AbbVie outside counsel also attended the interview.
109. When the interview began McKinley attempted to take notes, but Lee stated she could not do so. McKinley said she wanted to take notes and Lee said, "I am telling you not to take notes."
110. Lee began the interview by showing McKinley an e-mail sent by Mick Coleman, Marketing Director, from September 2016 Q4 regarding the Q4 2016 quarter's ASPs. Lee asked McKinley why Coleman sent the e-mail and why he sent the information to sales representatives if they were not able to discuss ASP.
111. McKinley informed Lee that she was unsure, but it was standard practice for the marketing director to send the information on a quarterly basis, and that the Office of Ethics and Compliance or legal approved the email.
112. McKinley shared that the Marketing Director prior to Mick Coleman sent the exact same emails quarterly, and McKinley indicated that she received these emails every quarter for the entire five years she was in the franchise.
113. Lee questioned McKinley about an e-mail from Coleman where Coleman asked McKinley if the two should discuss the quarterly ASP email with regional managers. McKinley had responded to the e-mail stating, "Do you mean on the next RM CC?" and the email chain stopped there.
114. McKinley informed Lee she did not believe there was ever any discussion with regional managers about ASP after that e-mail.
115. Next, Lee showed McKinley an e-mail written by Tom Christie, a Senior District Manager, regarding Trelstar's ASP, Eligard, Lupron, and historic market place information. Lee asked,

“Does this look like marching orders to you?”

116. McKinley replied, “No, it looks like a manager trying to give his team an overview of the marketplace, information, and education.”

117. Lee then stated, “It looks to me like there was a conversation and then there are marching orders.”

118. Lee asked McKinley how she communicated with her team in the field, and McKinley explained that she sent routine business by e-mail, through an iPad app the staff used, or by her monthly Vision Conference Calls.

119. McKinley further explained that her Vision Conference Calls were originally started by Sutcliffe when McKinley was still a Regional Manager. When McKinley took over the sales team, she turned these monthly conference calls into more motivational and inspirational calls with “actionables” that summarized a manager’s key takeaways and actions that the managers should take upon departing the conference call.

120. McKinley informed Lee that her Director of Commercial Strategy, Larry Duncan, created the slide decks for these calls and that she would review the slide decks with Sutcliffe before distributing prior to the call.

121. McKinley explained that she typically opened the calls, Sutcliffe discussed financial performance, and then they typically had a guest speaker with Regional Managers and District Managers listening on the call while marketing, training, and human resources frequently served as guest speakers on the calls.

122. Lee showed McKinley two e-mails written by Jack Bauerle, Senior District Manager, to his team with a carbon copy to his Regional Manager, Chris Reichow. The e-mails contained success stories about accounts saved, with one containing a reference to ASPs by a Sales Repre-

sentative, Tracy Hoffman.

123. Lee asked McKinley if this reference was okay, and McKinley responded that Hoffman was new and possibly needed some more training.

124. Lee further asked McKinley if she recalled meeting with a client, Chesapeake Urology. Lee asked who attended the meeting, what they discussed, and if Coleman mentioned anything about \$15,000.

125. McKinley informed Lee the meeting was a general meet-and-greet introducing her as the new Sales Director and that Coleman did not mention \$15,000.

126. Next, Lee asked McKinley if she was familiar with the client Carolina Urology Partners and if she recalled a meeting with them.

127. McKinley responded that she was familiar with this client and a contentious meeting with them in October 2016.

128. Lee then showed McKinley an e-mail from April 2016, and McKinley informed Lee that the e-mail was not referring to the October 2016 meeting, but rather an e-mail written by North Carolina District Manager, Steve King, to his Regional Manager, Mike Dixon, about how the customer agreed to meet with AbbVie. King stated that McKinley did a great job addressing responsible pricing.

129. Lee asked McKinley what “responsible pricing” meant, and McKinley stated she did not recall saying that on the call and that she never responded to the e-mail, but that “responsible pricing” is part of the discussion of Lupron being a premium product.

130. Lee was adamant that McKinley must have actually used the phrase “responsible pricing” because King wrote it in quotation marks. McKinley indicated that the email did not say McKinley had used the phrase, but rather it was a phrase King used himself to summarize a discussion

with the customer.

131. McKinley informed Lee that if she did use the phrase “responsible pricing,” there was no reason to think it was a problem because in five years with the franchise she had never been trained not to use the phrase.

132. Lee referred back to the phrase “responsible pricing” several more occasions throughout the interview.

133. Lee showed McKinley a script of a role play entitled “Dr. Penny Pincher” created by AbbVie training and approved by medical regulatory. Lee asked what should happen to the representative and district manager who wrote the script and McKinley stated they likely needed more training.

134. Lee asked McKinley about a concept he termed “divest,” which he described as a representative saying to an account that AbbVie would pull resources from the account if they did not continue to use the product.

135. McKinley informed Lee that no one would ever say “divest” to an account.

136. Lee concluded his questioning by asking when field representatives were trained not to discuss responsible pricing.

137. McKinley stated she believed field representatives were taught about responsible pricing in Initial Sales Training Classes. McKinley further stated that if there was no training on the issue, there should be.

138. After the interview concluded, McKinley met with Sutcliffe, voiced her concerns over the training received, and asked Sutcliffe if McKinley should be more involved in training.

139. Sutcliffe told McKinley unequivocally that training was not McKinley’s responsibility.

140. McKinley further requested a meeting with Sales Training to discuss her concerns related

to Urology Training.

141. McKinley and Coleman met with Pablo Hernandez, Director of Sales Training, and Tyler Snell, Endocrinology Senior Training Manager, where McKinley voiced her concerns over consistency and accuracy of Urology training as well as feedback from a Urology Marketing Manager regarding frequent errors by an uncertified trainer in a recent class.

142. McKinley requested to Hernandez that those in attendance at this December 2016 class be retrained on Urology.

143. McKinley further suggested that the training department ensure all trainers conducting the classes were certified.

144. After the interviews, McKinley learned that prior to beginning the interviews, the training department had provided all training materials to OEC for review.

145. Review of the training materials revealed that the company had done no training on price, responsible price, or ASP; thus, the interviewers knew that the interviewees, including McKinley, had not been trained on these matters.

146. After the meeting with Lee, Sutcliffe requested a follow-up with McKinley to discuss the interview. Sutcliffe was shocked that Lee would question the quarterly ASP email sent by Coleman and the brand strategy.

147. Sutcliffe said something to the effect of, "All of those documents were approved and reviewed by Medical, Regulatory, Legal. It is not OEC's job to be questioning how we run our business."

148. On Lee's questioning of responsible pricing, Sutcliffe said something to the effect of "King's email did not say you said the phrase responsible price. He is just summarizing the meeting with the customer."

149. McKinley reviewed every Vision Conference Call slide deck throughout her nearly three-year tenure in the Sales Director role. The only conference call that addressed ASPs was held in September 2016. McKinley did not lead that discussion of ASPs.

150. Sutcliffe was present during the September 2016 Vision call, and as Vice President of Sales and Marketing should have stepped in if any guest speakers presented anything that was deemed unapproved messaging.

151. McKinley did not address ASPs as part of her action items in the September 2016 conference call, therefore she did not give any direction related to ASPs.

152. In March 2017, Sutcliffe delivered McKinley's annual performance review. McKinley received a 4, "Exceeds Expectations" rating for the year 2016.

153. AbbVie awarded McKinley a higher-than-average raise, 110% of her annual bonus, and 110% of her annual restricted stock units.

154. Sutcliffe told McKinley that AbbVie gave McKinley all of this as a nod to the "long career trajectory" she had with AbbVie.

155. In McKinley's performance review, Sutcliffe praised her for, inter alia, "Worked cross-functionally to define and gain approval for an appropriate and responsible Uro contracting/pricing strategy that allows for business/share retention." McKinley received a 4, "Exceeds Expectations" in this category, "Decide Smart and Sure."

156. In or about March 2017 Kevin Fitzgerald, AbbVie Legal, informed McKinley that they were putting together a LERN module and bigger training to prepare everyone for the new launches in Oncology and Women's Health.

157. Fitzgerald said that Karen Hale, Vice-President Chief Ethics and Compliance Officer, was "Putting a lot of pressure on Legal and all over them to get this completed quickly," refer-

ring to the investigation into the Tolmar letter.

158. Fitzgerald further stated to McKinley that he reviewed the materials from the OEC investigation and that “No heads will roll. No one will lose their job.”

159. On May 8, 2017, AbbVie terminated Kate McKinley.

160. AbbVie conducted McKinley’s termination via a meeting with Sutcliffe and Brad Dempsey, Human Resources Director, with a prepared statement that informed McKinley she was found to be in violation of policy for unapproved messaging or direction given.

161. McKinley asked what specifically she did that violated the policy, and Dempsey informed her they would not provide that information today or any day.

162. McKinley asked what her sales force would be told regarding her employment at AbbVie. Sutcliffe responded, “that a person we deeply respect is no longer with the company.”

163. Dempsey stated that when pressed, all that would be communicated internally and externally was that McKinley was no longer employed by AbbVie, along with the dates of her service.

164. McKinley asked if she would be receiving a severance and whether AbbVie would relocate her back to California where she and her family had moved from a year-and-a-half prior. She noted that the move had caused significant expense for her family, leading her husband to shut down his primary care physician practice.

165. Dempsey declined both requests.

166. Sutcliffe assured McKinley her privacy and Dempsey said company policy was not to discuss reasons for an employee’s departure,

167. Since McKinley’s termination, the company has repeatedly insisted to other members of the salesforce that it terminated McKinley because of information discussed during her OEC in-

interview during the following instances:

- a. Senior management, Jim Hynd, announced at a company meeting that headlines must be avoided about AbbVie propping up price;
- b. Hynd announced at a June sales meeting that he wished he could show the documents to the sales force that were used in the OEC investigations because then it would be clear why the eight (8) people were terminated. Hynd said the evidence was “black and white;”
- c. Hynd announced that those who were fired received severance for their years of service.
- d. At the June Sales Meeting, a member of the AbbVie legal team brought up the massive TAP settlement from 2001 and the recent CIA agreement as things the Company needs to avoid. Hynd also stated something to the effect that “AbbVie could not afford another CIA agreement.”
- e. When the sales force asked what they should state to customers who asked what happened, Marianne stated, “Tell them we are a compliant company.”
- f. In a meeting with the Regional Managers at AbbVie on May 10, the Regional Managers asked Jim Hynd why those terminated were terminated rather than given more training. Hynd responded by discussing the fear of another CIA, fear of the political environment, and how Johnson & Johnson is under investigation related to marketing practices in Immunology. He noted that it is the 5th year of AbbVie’s existing CIA, and explained that “there is no appetite for another \$1 billion ne.” He continued that this investigation was associated with a letter from a competitive company and “heightened visibility.” Hynd said to the RMs, “Imagine this

headline, 'AbbVie props up price. Government pays more.' We need to think about the bigger picture and the shareholders." He continued, "50% of AbbVie's revenues come through the Federal Government."

168. All these examples gave the entire sales organization and external customers the idea that McKinley must have done something wrong relating to customer interactions or external communication, causing reputational harm to McKinley.

AbbVie Completely Reverses Course on Approved Messaging

169. Since McKinley's termination, AbbVie has made wholesale revisions to its training on approved messaging related to pricing.

170. Per a training AbbVie conducted on June 2017, sales representatives received subsequent remedial training about messaging that contradicts what McKinley and her franchise were instructed to deliver.

171. This remedial training informed employees that communications and behaviors that had been common and encouraged were no longer permitted.

172. For example, messaging guidance provided to senior management, including district managers, said:

- a. Sales representatives could discuss billing codes (J-Code) associated with AbbVie products.
- b. Sales representatives could discuss "Publicly available information to third party payers' payment and/or reimbursement amounts for AbbVie products, but only in response to specific questions from HCP/Customers."
- c. Sales representatives could discuss pricing information regarding Lupron contract or Non-Contracted DTP price.

173. AbbVie provided the following specific guiding principles:

- a. “You may proactively discuss Lupron’s contracted or non-contracted DTP price. You can only discuss Lupron’s ASP (reimbursement) or J-Code (billing information) in response to a customer question using Medical/Regulatory-approved (M/R) materials;”
- b. “If asked about pricing and reimbursement, you may not discuss the impact of Lupron’s price on ASP or reimbursement or otherwise use reimbursement as a reason to purchase Lupron or not purchase a competitor’s product;”
- c. “The Beyond Suppression Offering is designed to assist with patient care and inventory management of Lupron, beyond suppression. The Beyond Suppression Offering is not intended to, and thus cannot be marketed as, alleviating an HCP’s administrative burden or facilitating clean reimbursement claims;”
- d. “Only use M/R resources for product promotion, even when discussing publicly available information. No ‘homegrown’ materials may be used (M/R-approved materials have an ePass number associated with them).”

174. On the topic of “Lupron Price,” AbbVie’s guidance states the following:

- a. “Representatives can proactively communicate the customer’s Lupron DTP price, and can negotiate price, if necessary.”

175. On the topic of “Lupron’s Average Selling Price (ASP),” AbbVie’s guidance states the following:

- a. “Representatives can reactively communicate Lupron’s ASP using M/R-approved materials. Representatives can also refer HCPs to the CMS website for Lupron’s current ASP. Representatives cannot use ASP or reimbursement as a reason to purchase Lupron or to not purchase another product.”

176. On the topic of “Lupron’s Price & Lupron’s ASP,” AbbVie’s guidance states the following:

- a. “Representatives can proactively provide Lupron’s contract price and reactively provide ASP. Both pieces of data can be shared in whatever order asked by the customer (i.e. What is my contract price? What is the Lupron ASP? Or vice versa?). Representatives may not engage in any additional reimbursement rate conversations and may not market the “spread” as a reason to purchase Lupron or to not purchase another product.”

177. On the topic of “Lupron’s J-Code,” AbbVie’s guidance states the following:

- a. “Representatives can reactively provide the Lupron J-Code (J9217) to customers using M/R approved material, but cannot reference the fact that the J-Code is shared with Eligard.”

178. On the topic of “Competitor’s Price or ASP,” AbbVie’s guidance states the following:

- a. “Representatives cannot share information about competitors’ price or ASP.”

179. For the first time ever, AbbVie trained the sales organization not to say “responsible price.”

180. These subsequent changes indicate that AbbVie recognized McKinley’s comments about lack of training in her OEC interview, the concerns she raised with Sutcliffe, and the concerns she raised with Training Leadership revealed serious, company-wide problems with False Claims Act compliance.

COUNT I
Retaliation
31 U.S.C. § 3730(h)

181. Plaintiff McKinley re-alleges and incorporates by reference each and every allegation set

forth in the foregoing paragraphs.

182. The False Claims Act, 31 U.S.C. § 3730(h), prohibits Defendant from retaliating against employees who engage in protected conduct by taking lawful actions in furtherance of an FCA claim or by making efforts to stop one or more violations of the FCA.

183. An employee need not actually file a *qui tam* suit or even know about the protections of Section 3730(h) to qualify for protection under the retaliation provisions of the FCA.

184. An employee who characterizes the employer's conduct as illegal or fraudulent or who tries to stop a false claim from being made engages in protected conduct.

185. McKinley engaged in protected activity when she participated in the OEC's required interview.

186. McKinley engaged in protected activity again when, during the interview, she raised concerns about the lack of training for representatives on discussing price and ASP with physicians.

187. And McKinley again engaged in protected activity when she voiced concerns to Sutcliffe and when she voiced her concerns about Urology training to Hernandez and Snell.

188. The OEC interview resulted from the 2016 Tolmar letter alleging violations of the False Claims Act and the Anti-Kickback Statute, so McKinley's participation in the interview was directly related to stopping potential violations of the False Claims Act, and the training deficiencies she identified could lead to False Claims Act or Anti-Kickback Statute violations.

189. AbbVie acknowledged the potential impact of the deficiencies McKinley identified, as it implemented new training on discussing pricing in June 2017 after terminating her.

190. McKinley suffered materially adverse action when AbbVie terminated McKinley's employment on May 8, 2017.

191. AbbVie retaliated against McKinley because she engaged in protected activity under the

FCA.

192. Upon her termination AbbVie HR told McKinley that it terminated her because of the content of her OEC interview, and the company has reiterated that position to the AbbVie sales force multiple times since McKinley's departure. This is direct evidence that the company terminated McKinley because of her protected activity.

193. There is sufficient temporal proximity to infer a causal connection between McKinley's protected activity and her termination.

194. AbbVie had no legitimate business reasons for firing McKinley, and its stated reasons for its adverse action against McKinley are pretext for a retaliatory motive.

195. McKinley suffered substantial monetary and non-monetary damages as a direct and proximate result of AbbVie's retaliation.

196. McKinley is entitled to such legal or equitable relief as will effectuate the purposes of the anti-retaliation provision of the FCA.

PRAYER FOR RELIEF

Plaintiff Kate McKinley prays this Honorable Court for judgment against Defendant and respectfully demands reinstatement or front pay, 2 times the amount of back pay, interest on the back pay, compensation for special damages sustained, reasonable attorney's fees, pre-judgment interest, court costs, and any other relief that this Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff Kate McKinley demands a trial by jury for any and all issues proper to so be tried.

Respectfully submitted,

/S/

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FILED

NOV 14 2017

THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

November 10, 2017

VIA COURIER

Thomas Bruton
Clerk of Court
Everett McKinley Dirksen
United States Courthouse
219 South Dearborn Street
Chicago, IL 60604

17 CV 8255
JUDGE CASTILLO
MAGISTRATE JUDGE GILBERT

RE: Kate McKinley v. AbbVie, Inc.

Dear Mr. Bruton:

Enclosed please find three copies of Mrs. McKinley's complaint, civil cover sheet, and summons, along with the filing fee, in the above-captioned matter **to be filed under seal.** Please file the original complaint under seal and cover sheet and kindly return date-stamped copies of all documents to the Employment Law Group, PC via the enclosed self-addressed envelope. Please note this is a related case to 1:17-cv-6696, *Scott Babjak v. AbbVie, Inc.*

Please note we are filing this complaint under seal at the Defendant's request.

Very Truly Yours,
The Employment Law Group, PC

/S/
R. Scott Oswald, Esq.

cc: Kate McKinley